NDA 18-587/S-023

Wyeth-Ayerst
Attention: Ms. Mary Alice Dankulich
150-B3 North Radnor Chester Road
St. Davids, PA 19087

Dear Ms. Dankulich:

Please refer to your supplemental new drug application dated August 24, 2000 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wytensin (guanabenz acetate) 4 and 8 mg Tablets.

We acknowledge receipt of your submission dated August 17, 2001 that constituted a complete response to our March 7, 2001 action letter.

This supplemental new drug application provides for final printed labeling revised by the addition of a **Geriatric Use** subsection at the end of the **PRECAUTIONS** section of the package insert as follows:

> **Geriatric Use**
> Clinical studies of Wytensin did not include sufficient number of subject aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.
>
> In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

In addition, we noted minor editorial changes.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling (package insert) included in your August 17, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Mr. Daryl Allis
Regulatory Health Project Manager
(301) 594-5309.

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Raymond Lipicky

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